

Evidence-based medicine and point-of-care testing

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Point-of-care testing provides rapid laboratory diagnostics close to the site of care. Quality assurance of POCT, however, requires significant resources that should be matched with improved patient outcome and benefit. Application of evidence-based medicine to POCT can critically assess the medical effectiveness of the test through a systematic review of the scientific literature.

Introduction

Evidence-based medicine is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients [1]. The practice integrates clinical experience with existing evidence from the scientific literature to optimize approaches to patient management.

The term, evidence-based medicine, has been popularized recently with the increased healthcare pressure for improving patient care, reducing medical errors, and managing available resources. The evidence-based process has spawned systematic reviews and the development of clinical practice guidelines for the care of patients with specific disorders.

With the volume of information that is being generated every day, it is difficult for clinicians to maintain currency on all the latest developments particularly for non-specialist general practitioners. Practice guidelines and critical pathways offer clinicians an optimized care plan for managing patients.

Physicians have criticized practice guidelines as dictating their practice of medicine. This is not true, since guidelines are intended to assist physicians and

other healthcare providers in clinical decision-making by describing generally acceptable approaches for the diagnosis, management, or prevention of specific diseases or conditions.

Guidelines should not be considered inclusive of all proper methods of care or exclusive of other methods of care reasonably directed at obtaining the same results. Each physician must still make final judgement regarding the care of an individual patient.

Evidence-based medicine and point-of-care testing

Point-of-care testing (POCT) is a field that is ready for the application of evidence-based medicine. Nearly 25 % of all in-vitro laboratory testing is currently being conducted outside of a core laboratory, amounting to a USD 4.9 billion annual world-wide market that is increasing at a projected growth rate of 12 % yearly [2].

Almost half of this POCT market is conducted in a physician's office laboratory, with the other half split between hospital and home patient self-testing.

With such a rapid rise in POCT, quality issues have been an increasing concern. Self-management blood glucose devices represent the largest number of complaints filed with the U.S. Food and Drug Administration for any medical device, including 16 deaths and over 3200 incidents [3].

Poorly maintained urinometers and blood gas analyzers can be reservoirs for nosocomial antibiotic-resistant organisms [4, 5]. A recent Office of the Inspector General (OIG) reported that half of the state inspection agencies found problems with waived and provider-performed microscopy laboratories [6].

Fifteen states mentioned concerns about POCT, specifically noting that laboratories did not have written procedures; were not following manufacturer's instructions; failed to identify incorrect test results; had untrained staff; lacked quality controls; and had poor equipment, reagent storage, and record keeping.

Quality issues with POCT should not be surprising, since it is very difficult to obtain consistency of performance amongst the thousands of operators and hundreds of devices that are found in a typical modern health system.

Quality POCT results, therefore, requires standardized operator training, initial device validation, and ongoing management of competency and quality control review. What is the value and risk to patient care of a rapid test that generates the wrong results because of poor quality? The need for quality is therefore paramount in the testing process.

Given the significant resource expenditure to maintaining quality testing on the medical unit, laboratorians and clinicians should question the value of POCT, and specifically the value of obtaining a faster result to the care of a patient. While vendors have marketed the convenience of POCT, a critical assessment of whether POCT actually leads to better patient outcome is needed.

Is POCT worth the cost of the resources we are spending? This is where evidence-based medicine can assist in delineating POCT benefits, the scientific research available, and the weight of evidence either supporting or discouraging POCT implementation.

A critical assessment of gastric occult blood testing

Occult blood and pH tests in gastric fluid have been available for several years and are widely utilized on medical inpatients.

However, gastric occult blood testing is entirely manual, and absolute compliance with manual documentation for operator training, test analysis, resulting, quality control, and billing is difficult to achieve under U.S. CLIA '88, state and private accreditation standards. We, thus, sought to determine the medical effectiveness of this test and patient benefit in our institution.

The current utilization of gastric occult blood testing was the first step in our investigation. Records indicated the purchase of 296 boxes of cards (40 cards per box) by 15

medical units, and 637 bottles of developer purchased by 16 medical units over the previous year.

There is the potential that staff are misusing gastric occult blood test developer for fecal occult blood testing (and vice-versa), since gastric occult blood developer was purchased by three medical units not purchasing gastric occult blood cards.

A survey of practice was conducted on the medical units that purchased cards or developer in the past year. Gastric occult blood testing was utilized on patients presenting with gastric complaints, primarily on patients from the gastrointestinal (GI), surgery, and cancer services.

To our surprise, the gastric occult blood card was primarily used for pH testing rather than for occult blood. Testing volume varied between medical units from 1 to over 100 per week. The total hospital testing volume was estimated from purchasing records at 11,840 annually, while the number of tests officially billed was only 12 (0.1 %).

A systematic review of the scientific literature was conducted through Medline OVID and Practice Guideline databases using the key words; "gastric occult blood", "Gastrocult", and "occult blood". Medline OVID located 182 citations that were manually reviewed. Most citations were related to test interferences and analytical performance.

While the gastric occult blood test has been utilized in randomized drug and treatment trials to monitor gastric bleeding, no randomized clinical trials were found to specifically address gastric occult blood test effectiveness on patient outcomes. Searching for "occult blood" located 3061 additional citations that were not comprehensively reviewed.

The EBM Reviews database of abstracts of reviews of effectiveness retrieved no matches. The Cochrane Database of systematic reviews matched seven citations to "occult blood" that were all stool rather than gastric related. The National Guideline Clearinghouse also

matched two citations that were related to occult blood in stool rather than gastric fluid [7, 8].

Zynx Database located another two citations that were pertinent to gastric occult blood. The first study noted only a 79 % sensitivity and a 55 % specificity compared to endoscopy [9].

Nasogastric tube aspirates do not provide accurate information regarding the presence of bile and the location or activity of bleeding (Class B Evidence - Non-randomized, prospective, controlled trials that make comparisons between contemporaneous patients, or between current and former patients including noncontrolled case series of 10 or more patients and studies which make use of retrospectively acquired data).

The second study noted that a negative nasogastric aspirate is of questionable value in determining the presence of active bleeding when compared to endoscopy results (Class B Evidence) [10].

Based on the lack of supportive literature, a recommendation was made to discontinue this test. Our clinical practice guideline was updated to stress the importance of the nasogastric aspirate. While an upper gastrointestinal source of bleeding is confirmed by the presence of blood or coffee grounds, a non-bloody aspirate can be seen in 15 % of patients with a true upper source.

The finding of red blood in the aspirated fluid is indicative of active bleeding and is associated with the highest risk of complication, while a clear aspirate identifies a patient at lower initial risk (Class A Evidence - Evidence from at least one randomized, usually small, controlled trial or from a meta-analysis of randomized control trials in which the confidence interval for the treatment effect overlaps the minimal clinically important benefit).

Data may have high false-positive or high false-negative errors) [11, 12]. The use of fecal or gastric occult blood tests in the setting of acute upper gastrointestinal bleeding is not warranted. Decisions should be based on the gross appearance of the aspirate (Class E Evidence -

Evidence from opinions of respected authorities, based on clinical experience or from descriptive studies; well-designed non-experimental studies such as comparative studies; case series without controls; or reports of expert committees) [13].

A letter was sent to all staff announcing the gastric occult blood test discontinuation and highlighting the reasoning behind the decision as:

- There is no peer-reviewed literature indicating the improved outcome of patients based on the use of gastric occult blood.
- Use of the test cards to detect occult blood after placement of a nasogastric tube can lead to positive result merely due to the trauma of tube insertion.
- Overt bleeding that is a medical concern is generally visible in gastric fluid.
- pH is medically useful, and pH paper is a better alternative. pH paper is easier to quality control and already available on the medical units at a lower cost.
- Elimination of gastric occult blood testing would reduce the burden of training and competency for POCT on the nursing staff and would additionally reduce the risk of developer mix-up with the fecal occult blood test cards.

Gastric occult blood testing was discontinued without complaint or clinical incident. In the months following discontinuation, the core laboratory only received several requests for gastric occult blood testing. These were mostly due to a lack of staff awareness of the test's effectiveness and test discontinuation.

All tests were overtly brown, coffee ground appearance, and positive by gastric occult blood. Elimination of gastric occult blood testing has led to financial and labor savings (Table I). Similar savings have recently been noted in other institutions as well [14].

Cost estimates to support gastric occult blood testing	
Reagent (11,840 tests/year)	
Cards	USD 20,288
Developer	USD 4,293
Labor	
Nursing (5 min/test, 988 hrs = 0.47 FTE at USD 45,000/yr)	USD 21,346
Competency (1100 nurses x 15 mins, 275 hrs = 0.13 FTE)	USD 5,950
Lab oversight (4 hrs/mo x 15 units x 12 mos = 0.35 FTE)	USD 15,577
Total annual cost	USD 67,454

Table I: Cost estimates for annual support of gastric occult blood testing. Reagent costs represent actual direct cost of cards and developer. Nursing labor of 5 minutes (min) per test was based on the average time to collect, apply, develop, and document the test result to the patient's chart.

Labor hours (hrs) are also presented in full-time equivalents based on a 40-hour work week at USD 45,000 per year. Annual competency estimates visual inspection of 1100 operators and documentation taking 7.5 minutes each for both the operator and the inspector. Lab oversight assumes only 1 hour per week of oversight per nursing unit.

By comparison, support of pH paper alone on the nursing unit would generate the same labor, but the expense for reagent is only USD 250 per year! By discontinuing gastric occult blood testing, the health system essentially saved almost 1 FTE or USD 67,454 a year, since pH paper was already being supported on these medical units.

Discussion

The evidence-based medicine process provides a means to critically assess the medical effectiveness of a laboratory test. However, when applied to POCT, evidence-based medicine does have some limitations.

First, there are multiple synonyms for POCT: near-patient, ancillary, bedside, satellite, decentralized, rapid testing, etc. Unbiased assessment of the literature requires comprehensive review of the literature, but most database searches are limited to matching exact terminology. Finding the pertinent references can be challenging with so many possible terms to search.

Second, grading schemes vary and are clinically focused. There is no standard evidence grading scheme and some organizations utilize an alphabetical scheme while other use numeric. For POCT, there are few randomized controlled trials. Most of the POCT literature consists of technical performance and comparisons to core laboratory methods.

If POCT compares to a core lab, it is “assumed” to produce the same clinical outcome as the core lab. Yet, POCT differs in sensitivity, specificity, accuracy, precision, and interferences from core laboratory methods. So, while POCT may agree with a core lab method, it does not necessarily mean that comparable outcomes will be obtained.

This emphasizes the need for clinical evaluations of POCT technologies and patient outcome data. Finally, POCT is a rapidly advancing field. The delay in peer-review until a study appears in print can actually be longer than the current POCT development time. Thus, some POCT studies are already outdated by the time they are published.

Assessment of the medical effectiveness of gastric occult blood testing in our institution raised several important conclusions about POCT. Evidence-based medicine is not only useful when investigating the implementation of new technologies, since a number of point-of-care tests have become a traditional practice in hospitals without ever questioning their effectiveness.

Pathology should take a leading role in questioning the medical effectiveness of testing that is draining hospital resources without overt patient benefit. Requiring evidence of patient outcome will become increasingly important in light of the recent staff shortage

experienced in both nursing and laboratory professions, and the amount of labor required to maintain and document quality POCT on the medical unit.

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